

REMARKS

Claims 1-5, 7, 10, 31 and 33 are presently pending. Support for new Claim 33 is found in the specification as filed, for example at page 15, line 20 through page 16, Table 2 and at page 17, line 16 through page 18, line 14. No new matter has been added herewith. The following addresses the substance of the Office Action.

Obviousness

Hashimi et al. in view of Tamura et al. and Folds et al.

Claims 1-9 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Hashmi et al. (WO 01/07079), Tamura et al. (1975 *Immunology* 28:909-924) and Folds et al. (1983 *J Clin Microbiol* 18:321-326). Hashmi et al. relates to a vaccine formulation that provides for the extended release of antigenic material over time. The Examiner acknowledged that this reference fails to teach progressively increasing doses of the antigenic material over time. The Examiner relied on Tamura et al. and Folds et al. to support the conclusion that it would have been *prima facie* obvious to modify the teachings of Hashmi et al. by the teachings of Tamura et al. and Folds et al. and arrive at the presently claimed methods. However, as discussed below, there are no teachings in any of the cited references with regard to progressively increasing doses of one or more biologically active agents.

The main focus of the presently claimed invention is on increasing an antibody response to an antigen. Accordingly, Claim 1 is limited to "A process for stimulating an antibody response to an antigen in an animal comprising administering to said animal on a single occasion said antigen in a form that releases over a predetermined period of time progressively increasing doses of said antigen in the same form, thereby stimulating said antibody response to said antigen in said animal." The Applicant notes that, while Tamura et al. disclose two doses of SRBC, and that anti-SRBC antibodies are produced, the second dose of SRBC is not necessarily higher than the first dose. Moreover, the first dose is SRBC alone while the second dose is of SRBC conjugated to TNP. Thus, the second dose of SRBC is not in the same form as the first dose.

Unexpected Results

The presently claimed invention produced unexpected results that could in no way have been predicted by one having ordinary skill in the art. Referring to Figure 5 and the accompanying text at page 18, lines 9-14 of the specification as filed, when progressively-increasing doses of an antigen were administered to an animal in accordance with the presently

claimed invention, the antigen was surprisingly more effective in stimulating an early and more robust antibody response compared to a conventional vaccination regimen. Nothing in the cited prior art or any other knowledge of a person having ordinary skill in the art, would lead such a person of ordinary skill in the art to expect such an unexpected improvement in antibody response.

Based on the combined teachings of Hashimi et al., Tamura et al. and Folds et al., there was no reason to believe that, relative to conventional immunization regimens, an earlier and more robust antibody response could be stimulated by administering progressively increasing doses of an antigen. As such, the unexpected results following the presently claimed process are evidence against any alleged *prima facie* obviousness. Accordingly, the Applicant respectfully requests that the rejection in view of the cited references be withdrawn.

Hashimi et al. in view of Tamura et al., Folds et al. and Sako et al.

Claims 10 and 31 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Hashmi et al., Tamura et al. and Folds et al. (as discussed *supra*) in further view of Sako et al. (WO 94/06414). However, in view of the remarks above, particularly with regard to the unexpected results obtained with the presently claimed process, Sako fails to add any additional information to the combined teachings of Hashmi et al., Tamura et al. and Folds et al. that would have provided any reason to believe that an earlier and more robust antibody response could be stimulated by administering progressively increasing doses of an antigen. Accordingly, the Applicant respectfully requests that the rejection of Claims 10 and 31 be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not

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reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
JAMES68.023APC	11/908708	AGENT ADMINISTRATION	05-Aug-2009

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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